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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,497	03/16/2004	Matthew During	102182-0036	3969

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EXAMINER	
FALK, ANNE MARIE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,497	DURING ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-48 are pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-42, drawn to (1) a method for treating a neurodegenerative disease in a subject, (2) a method for treating epilepsy in a subject by delivering a vector encoding a glutamic acid decarboxylase (GAD), (3) a method for treating epilepsy in a subject by delivering an adeno-associated viral (AAV) vector encoding GAD, and (4) a method of altering expression of GAD in a region of the central nervous system (CNS) of a subject with epilepsy, classified in class 424, subclass 93.2 and class 514, subclass 44.

II. Claims 43-48, drawn to a vector comprising a nucleotide sequence encoding GAD, classified in class 435, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, i.e. the vector of the invention of Group II, can be used to transfect cells in culture to produce a host cell expressing GAD, which can then be used to conduct *in vitro* assays, thus demonstrating a materially different process of using that product and meeting criteria (2). Thus, the vector of the

invention of Group II is patentably distinct from the method of the invention of Group I, which involves *in vivo* administration of the vector.

Each of the inventions of Groups I and II requires consideration of separate issues relating to assessment of novelty, obviousness, utility, written description, and enablement. For example, the invention of Group I requires consideration of issues relating to enablement for treating a neurodegenerative disease, which is not required for examination of the invention of Group II because the vector encoding GAD has uses other than for treating disease. As a further example, the invention of Group II requires consideration of issues relating to novelty of the vector encoding GAD, which is not required for examination of the invention of Group I because even if the vector encoding GAD is not novel, the method of treating a neurodegenerative disease may still be novel and non-obvious, which requires a separate and independent assessment. Furthermore, the searches for the inventions of Groups I and II are not coextensive. For example, a search for the vector of the invention of Group II would not necessarily identify art teaching the method of the invention of Group I, because the vector would be expected to have uses that are separate and unrelated to its use in treating a neurodegenerative disease. Additional searching would be required to cover the method of the invention of Group I. Likewise, a search for the method of the invention of Group I would not be considered a comprehensive search for the vector of the invention of Group I because before successful treatment of a neurodegenerative disease is reported, the art is likely to include research papers that are directed to evaluation of vectors, to identify vectors that transduce efficiently and provide appropriate levels of expression in the desired cell type, and a search for a method of treating a neurodegenerative disease would not identify such papers. Thus, search and examination of both inventions in a single patent application constitutes a serious burden on the Office, as each group requires a separate search and consideration of issues separately applicable to each group.

With regard to burden, MPEP § 808.02 states that, to establish that there would be a serious burden on the examiner if restriction is not required,

> "the examiner must show by appropriate explanation one of the following:
> (A) **Separate classification thereof:** This shows that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification." (emphasis original)

Thus, to establish that a serious burden exists, it is sufficient to show separate classification of the inventions. The instant inventions have separate classifications and require separate search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species

Part 1. Upon election of Group I or II, Applicant is required to elect one of the species listed below. This application contains claims directed to the following patentably distinct species of the claimed invention, covering the following different types of gene transfer vectors, as set forth in the claims:

A. Adenovirus vector.

B. Herpes virus vector.

C. Parvovirus vector.

D. Lentivirus vector.

E. Adeno-associated viral vector.

F. Liposome-mediated delivery vector.

The different types of gene transfer vectors as outlined in the species election requirement A-F represent distinct inventions because they are drawn to different vectors that are structurally and functionally distinct, having very different modes of action. The different gene transfer vectors require separate searches. The vectors are not so related as to be considered obvious variants. Furthermore, there is nothing on the record to suggest that the vectors are obvious variants.

Part 2. Upon election of Group I, Applicant is further required to elect one of the species listed below. This application contains claims directed to the following patentably distinct species of the claimed invention, covering the following brain regions, as set forth in the claims:

A. basal ganglia

B. subthalamic nucleus (STN)

C. pedunculopontine nucleus (PPN)

D. substantia nigra (SN)

E. thalamus

F. hippocampus

G. amygdala

H. hypothalamus

I. cortex

The different brain regions as outlined in the species election requirement A-I represent distinct inventions because they are drawn to different brain structures requiring different searches for each region. The different brain regions are structurally and functionally diverse. The regions are not so related as to be considered obvious variants. Furthermore, there is nothing on the record to suggest that the different brain regions are obvious variants.

Part 3. Upon election of Group I, Applicant is further required to elect one of the species listed below. This application contains claims directed to the following patentably distinct species of the claimed invention, covering the following diseases, as set forth in the claims:

A. Parkinson's disease

B. Alzheimer's disease

C. Senile dementia

D. Amyotrophic Lateral Sclerosis (ALS)

E. Epilepsy

Although **Claim 13** recites "amyloid lateral schlerosis" this term could not be interpreted because the art does not disclose any disease called "amyloid lateral schlerosis." **Appropriate correction is required.** At page 4, paragraph 2, the specification contemplates using the method of the invention to treat amyotrophic lateral sclerosis, and therefore this disease has been included among the species for election.

The different diseases as outlined in the species election requirement A-E represent distinct inventions because they are drawn to treatment of distinct diseases which have different etiology, different symptoms and deficits, and different clinical outcomes requiring different searches for each disease. The different diseases affect different areas of the central nervous system and are clinically divergent. The diseases are not so related as to be considered obvious variants. Furthermore, there is

nothing on the record to suggest that the different diseases are obvious variants such that a method of treating one disease would render the method obvious for treating other diseases.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1 and 43 are generic.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species associated with the elected invention, even though this requirement is traversed.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim

will be rejoined in accordance with the provisions of MPEP § 821.04. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). See also MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER